



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,894	08/11/2006	Martin Stephen Clough	70240USPCT	3379

22847 7590 05/20/2011
SYNGENTA BIOTECHNOLOGY, INC.
PATENT DEPARTMENT
3054 CORNWALLIS ROAD
P.O. BOX 12257
RESEARCH TRIANGLE PARK, NC 27709-2257

EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
----------	--------------

1648

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

05/20/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP.SBI@syngenta.com

Office Action Summary	Application No.	Applicant(s)	
	10/551,894	CLOUGH ET AL.	
	Examiner	Art Unit	
	SHANON A. FOLEY	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11-20,24 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11-20,24 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 3 and 11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 3 specifies that the plant pests are insects. However, claim 1, as amended, indicates that the pests which feed on plants are insects. Therefore, claim 3 fails to further limit claim 1.

Claim 11 requires that the first insecticidal toxin is an insecticidal toxin. However, this limitation is already recited in section (a) of claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-9, 11-13, 15-20, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roush (Phil. Trans. R. Soc. Lond. B. 1998; 353: 1777-1786), Schnepf et al. (Microbiology and Molecular Biology Reviews. 1998; 62 (3): 775-806) and English et al. (US 6,023,013), all of record.

Roush teaches a method of controlling insects by providing a locus in which plant pests feed comprising a first region of plants that express a first insecticidal toxin, but not the second,

Art Unit: 1648

and a second region of plants that express a second insecticidal toxin, but not the first. In addition, Roush teaches that the first insecticidal toxin have different binding sites and different modes of action, wherein a pest which develops resistance to the first toxin does not develop resistance to the second toxin. See the last paragraph of sections “(a) Options for two-toxin deployment” beginning in the first column on page 1780 and through section “(d) Effect of Mortality of susceptible homozygotes on pyramids” on page 1781. Roush teaches that one of the mechanisms for deployment of the toxins is simultaneous distribution within the same field or different fields, i.e. random distribution, see the first paragraph under section “a”. Roush also teaches providing a region of plants that are non-insecticidal, see section “(c)”, bridging pages 1780-1781. In the last paragraph of section “(c)”, Roush specifically teaches that cotton plants possess different toxins.

Claims 5-9 require various distances between the first region and the second region, ranging from within a mile to interspersed regions.

Roush teaches that the toxins are deployed simultaneously in different varieties, such as in a seed mix within the same field or neighboring fields, see the first paragraph of section “(a)” on page 1780.

While Roush does not specifically teach seeding of a second region within a mile or adjacent or around the perimeter of the first or alternating strips within the first, these architectural features would have been prima facie obvious design alternatives to one of ordinary skill in the art at the time the invention was made since a seed mix within the same field or neighboring fields, as taught by Roush, encompasses various patterns of seed planting.

Instant claims 17-19 require that at each locus comprises at least between 5% to 50% of the two toxins, respectively.

See the teachings of Roush above. While Roush does not specifically teach a percentage of each toxin present at each locus, Roush depicts a refuge area of less than 5% within locuses comprising two-toxin plants, see the lower left side of Figure 2 on page 1780 and the first paragraph under section "(c)". Provided that the two different locuses comprising each toxin are distributed evenly, each locus comprising a single toxin would approach 50%. In addition, Roush also teaches that the recommendations in Australia is that at least 20% of cotton and maize should be non-transgenic, see the top of the second column on page 1778 and Figure 2 on page 1780.

One of ordinary skill in the art at the time the invention was made would have been motivated to vary the percentage of toxin present at each of the two locuses with the percentage amount of refugia provided, with a reasonable expectation of success, to delay the onset on insect resistance to the toxins, see section "(c)" and Figure 2. One of ordinary skill in the art at the time the invention was made would have been further motivated to increase the percentage of refugia provided, thereby decreasing the percentage of the two transgenic locuses, to ensure that a large proportion of pests develops on the non-transgenic refuge hosts, see the top of the second column on page 1778 and Figure 2 on page 1780.

Roush does not teach or suggest that the first toxin is a Bt crystal protein of the second toxin is a Bt VIP protein, or vice versa. Roush also does not teach that the first or the second toxin is Bt Cry1Ac.

Art Unit: 1648

Schnepf et al. teach that Bt VIP proteins are pesticidal and unrelated to the Cry proteins, see the second full paragraph of the second column on page 776. Regarding Cry1Ac, Schnepf et al. teach that the protein has affinity for aminopeptidase N, see the paragraph bridging pages 783-784.

One of ordinary skill in the art at the time the invention was made would have been motivated to express Bt VIP and Cry1Ac as pesticidal toxins in the pyramided gene expression taught by Roush to delay insect resistance by providing a broad range of toxin divergence, see the first paragraph of section "(b)" on page 1780 of Roush. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for expressing the Bt VIP and Cry1Ac toxins, taught by Schnepf et al., individually, in the method of Roush since Roush specifically teaches that "the two toxins expressed should be as unrelated as possible", see the first paragraph of section "(b)" on page 1780 of Roush.

See the teachings of Roush and Schnepf et al. above. Neither reference teaches that the first toxin is Bt Cry3A and that the second toxin is Cry3B.

Schnepf et al. also teach Cry3A and Cry1A only show a 36% sequence identity, despite the similarity in 3D structure, see Figure 1 on page 779, the first paragraph under "Toxin Structure" on page 779 and Figure 4 on page 782. In addition, English et al. teach structural differences between the two toxins, see column 87, line 59 to column 88, line 2.

One of ordinary skill in the art at the time the invention was made would have been motivated to express Cry3A and Cry3B as pesticidal toxins in the pyramided gene expression taught by Roush to delay insect resistance by providing a broad range of toxin divergence, see the first paragraph of section "(b)" on page 1780 of Roush and/or to provide an effective

Art Unit: 1648

insecticide against the Colorado Potato Beetle and the southern corn rootworm, see column 35, lines 39-47 of English et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for expressing the Cry3A and Cry3B toxins, taught by Schnepf et al. and English et al., individually, in the method of Roush since Roush specifically teaches that “the two toxins expressed should be as unrelated as possible”, see the first paragraph of section “(b)” on page 1780 of Roush and Schnepf et al. and English et al. teach structural divergence between the two toxins.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roush as applied to claims 1, 3-9, 11-13, 15-20, 24 and 26 above, and further in view of Driver et al. (US 5,640,804, cited in the IDS).

Claim 14 requires that the plants expressing the first toxin and the plants expressing the VIP protein are from different genera.

See the teachings of Roush et al. At the beginning of section “(a)” on page 1780, Roush teaches that toxins may be deployed individually “in different varieties...as a seed mix”. Whether the “different varieties” discussed by Roush is referring to the different toxins or different varieties of plants is unclear. However, it is clear that Roush intends a mixture of different gene expressions in the same field or neighboring fields. Therefore, while Roush does not clearly indicate that the plants expressing the first and second toxins are from different genera, Driver et al. teach different plants planted adjacent to each other, see claims 1, 7, 11 and 13.

One of ordinary skill in the art at the time the invention was made would have been motivated to provide a plant expressing a first toxin with a different genera plant expressing a

Art Unit: 1648

second toxin to control insect pests, see claim 1 of Driver et al and section “(a)” on page 1780, Roush. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for providing a plant expressing a first toxin with a plant expressing a second toxin to control insect pests, as taught by Roush, of different genera, taught by Driver et al. since Roush teaches that toxins may be deployed individually “in different varieties...as a seed mix”, see section “(a)” on page 1780.

Response to Arguments

Applicant summarizes the teachings of Roush and concludes that Roush teaches away from mosaics and sequentialling in favor of pyramiding. Applicant summarizes the instant invention, which requires a locus comprising two regions, each comprising plants that produce different insecticidal toxins as an effective tool for controlling insects better than techniques requiring refugia. Applicant asserts that other teachings of Roush are irrelevant and deficient because the reference requires a refuge, which is in contrast to the instant invention.

Applicant’s arguments and a review of Roush have been fully considered, but are found unpersuasive. However, applicant’s description of the instant invention is accurate and in this regard, Roush teaches a method of controlling insects by providing a locus comprising two regions. The first region of plants express a first insecticidal toxin and the second region of plants express a second insecticidal toxin. In addition, Roush teaches that the first insecticidal toxin have different binding sites and different modes of action, wherein a pest which develops resistance to the first toxin does not develop resistance to the second toxin. See the last paragraph of sections “(a) Options for two-toxin deployment” beginning in the first column on page 1780 and though section “(d) Effect of Mortality of susceptible homozygotes on pyramids”

Art Unit: 1648

on page 1781. Roush teaches that one of the mechanisms for deployment of the toxins is simultaneous distribution within the same field or different fields, i.e. random distribution, see the first paragraph under section "a". Roush also teaches providing a region of plants that are non-insecticidal, see section "(c)", bridging pages 1780-1781. In the last paragraph of section "(c)", Roush specifically teaches that cotton plants possess different toxins. Therefore, Roush teaches the limitations required of the instant invention (and summarized by applicant above), which requires a locus comprising two regions, each comprising plants that produce different insecticidal toxins as an effective tool for controlling insects.

Regarding the assertion that the instant locus is more effective than those insecticidal techniques that use a refuge, there is no evidence or data supporting this assertion. Applicant has provided no comparable data that would suggest that the instant locus claimed is a better insect resistance technique than insecticidal crop techniques that require refuge. In fact, the instant invention does not exclude using refugia in conjunction with the instant locus technique, see lines 10-11 on page 5 of the instant disclosure, as well as instant claim 4, which requires a region of non-insecticidal plants. Therefore, the instant locus "comprising at least two regions" does not exclude a refuge region.

Applicant also argues that the teachings of Driver et al., Schnepf et al. and English et al. fail to overcome the deficiency of Roush.

Applicant's arguments have been fully considered, but are found unpersuasive since there are no deficiencies in the teachings of Roush against the instant claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANON A. FOLEY whose telephone number is (571)272-0898. The examiner can normally be reached on flex, generally M-F 7AM - 3 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on (571) 272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SHANON A. FOLEY/
Primary Examiner, Art Unit 1648